



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 10 2001

Ms. Rahael Judkins  
Manager of Regulatory Affairs  
Jelenko Company  
99 Business Park Drive  
Armonk, New York 10504

Re: K003603  
Trade Name: Bio Herador SG, Bio Herador GG, Herador S  
Bio Herador N, Herabond, Heraloy G, Albabond, Bio  
Maingold SG, Maingold SG, Hera GG, and Mainbond EH  
Regulatory Class: II and II  
Product Code: EJT and EJS  
Dated: November 17, 2000  
Received: November 21, 2000

Dear Ms. Judkins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

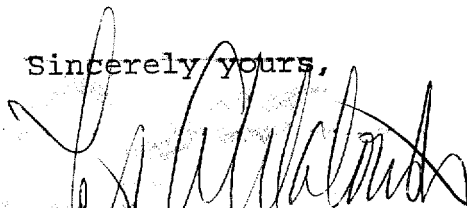
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE

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510(k) Number: K003603

Device Name (s):

Bio Herador SG	Herabond	Maingold SG
Bio Herador GG	Heraloy G	Hera GG
Herador S	Albabond	Mainbond EH
Bio Herador N	Bio Maingold SG	

Reconstruction of porcelain-to-metal ~~dental restorations~~/reconstruction of dental restorations.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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CONCURRENCE OF CHRD, OFFICE OF DEVICE EVALUATION (OED)

Susan Kanner  
(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

Prescription use ☒  
(Per 21 CFR 801.109)

510(k) Number K003603 OR Over-The-Counter Use